

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	
	)	MDL NO. 1203
	)	
	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203
	)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8515

Bartle, C.J.

August 19, 2010

Donna J. Pickering ("Ms. Pickering" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, Dr. Evans has signed in excess of 322 Green Forms on behalf of claimants seeking Matrix Benefits. See Pretrial Order ("PTO") No. 8412 (Mar. 9, 2010). Based on an echocardiogram dated January 7, 2002, Dr. Evans attested in Part II of Ms. Pickering's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral

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2. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$545,310.<sup>3</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Thomas B. Moore, M.D., stated that claimant had moderate mitral regurgitation. Dr. Moore, however, did not specify a percentage as to claimant's level of mitral regurgitation.<sup>4</sup> Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In December, 2003, the Trust forwarded the claim for review by Meldon C. Levy, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Levy concluded that there was no

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3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

4. Claimant also submitted an echocardiogram report prepared in May, 2002 by Dr. Evans based on her January 7, 2002 echocardiogram. In this report Dr. Evans stated that "[t]he mitral valve shows moderate mitral regurgitation. The jet ratio is 25% RJA/LAA."

reasonable medical basis for the attesting physician's finding that Ms. Pickering had moderate mitral regurgitation because her echocardiogram demonstrated only physiologic mitral regurgitation.<sup>5</sup> In support of this conclusion, Dr. Levy explained that "[t]here is no significant color flow evidence of mitral regurgitation on this tape. There is a pulsed wave signal consistent with only physiologic mitral regurgitation."

Based on Dr. Levy's finding that claimant had physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Pickering's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant submitted affidavits from Dr. Evans, Gregory R. Boxberger, M.D., F.A.C.C., and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Evans confirmed his previous finding that claimant had moderate mitral regurgitation with a RJA/LAA ratio of 25%. Dr. Boxberger stated that "[t]he echocardiogram tape in question shows 'moderate' mitral valve regurgitation with a RJA/LAA ratio of 25%." Dr. Francisco also concluded that

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5. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or  $\leq$  5% RJA/LAA."

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Pickering's claim.

claimant's echocardiogram tape showed moderate mitral regurgitation, and found "a RJA/LAA ratio of approximately 30%." Claimant argued, therefore, that she had established a reasonable medical basis for her claim because three Board-Certified Cardiologists independently agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (emphasis in original).

The Trust then issued a final post-audit determination, again denying Ms. Pickering's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Pickering's claim should be paid. On December 6, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4197 (Dec. 6, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 3, 2005, and claimant submitted a sur-reply on February 18, 2005. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Pickering repeats the arguments she made in contest; namely, that the opinions of Dr. Evans, Dr. Boxberger, and Dr. Francisco provide a reasonable medical basis for the finding of moderate mitral regurgitation. She also argues that the conclusions of the reviewing cardiologist, Dr. Moore, provide a reasonable medical basis for the attesting physician's representation. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Levy. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Pickering contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim because Dr. Evans, Dr. Boxberger, and Dr. Francisco do not address Dr. Levy's specific finding that claimant had only physiologic mitral regurgitation. The Trust also contends that inter-reader variability does not establish a reasonable medical basis for Ms. Pickering's claim because "Dr. Levy did not merely disagree with the representation of [claimant's] Attesting Physician and experts that [claimant] has moderate mitral

regurgitation - Dr. Levy found no reasonable medical basis for it."<sup>8</sup>

In her sur-reply, claimant argues that there is a reasonable medical basis for her claim because "it would be extremely unlikely that all of these highly trained and experienced cardiologists are wrong ...." (emphasis in original). In addition, Ms. Pickering reiterates that the concept of inter-reader variability provides a reasonable medical basis for the representation of moderate mitral regurgitation by Dr. Evans.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Pickering had moderate mitral regurgitation. Specifically, Dr. Abramson determined that:

In reviewing the transthoracic echocardiogram of 1/07/02, my visual estimate is that there is only mild mitral regurgitation. The parasternal views are of poor quality, and no mitral regurgitation is seen. The apical views are better quality. There is only mild mitral regurgitation that is evident only in

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8. The Trust also argues that claimant's additional expert reports should be disregarded because Ms. Pickering did not submit a list of previous cases in which the respective experts have served and the Audit Rules prohibit the submission of more than one expert report. We disagree. As we previously have held, requiring disclosures pursuant to Rule 26(a)(2) of the Federal Rules of Civil Procedure would serve no purpose given the prohibition on discovery contained in the Audit Rules. See, e.g., PTO No. 6996 at 7 n.10 (Feb. 26, 2007). Moreover, we previously have declined to impose a limitation on the number of verified expert opinions that may be submitted by a claimant. See, e.g., PTO No. 7111 at 6 n.9 (Apr. 12, 2007).



the apical-4-chamber view. It is a very short jet, occupying less than half of systole (which confirms that it is only mild). I am unable to measure the RJA/LAA ratio because it is too small a jet, but it is clearly <10%.

There was no mitral regurgitation tracing on the tape (1/07/02) for me to critique. The mitral regurgitation jet is not an eccentric jet. It is a tiny central jet.

In summary, it would be impossible for a reasonable echocardiographer to interpret the severity of this mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that [claimant] has moderate mitral regurgitation, even taking into account inter-reader variability.

In response to the Technical Advisor Report, claimant notes that Dr. Evans, Dr. Francisco and Dr. Boxberger all found that she had moderate mitral regurgitation, a determination that was supported by the original reviewing cardiologist, Dr. Moore. Claimant contends, therefore, that it is error for Dr. Abramson to assert that no cardiologist could have reasonably concluded that Ms. Pickering had moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately refute the conclusions of the auditing cardiologist or the Technical Advisor. Claimant does not rebut the auditing cardiologist's determination that "[t]here is no significant color flow evidence of mitral

regurgitation on [claimant's] tape."<sup>9</sup> Nor does claimant challenge the Technical Advisor's conclusion that "[t]here is only mild mitral regurgitation that is evident only in the apical-4-chamber view. It is a very short jet, occupying less than half of systole (which confirms that it is only mild)." Although Ms. Pickering submitted the reports of several cardiologists, neither claimant nor her experts identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor. Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Pickering had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrates an RJA/LAA

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9. For this reason as well, we reject claimant's argument that the auditing cardiologist substituted his personal opinion for the diagnosis of the attesting physician.

ratio of less than 10% and the auditing cardiologist determined that claimant had only physiologic mitral regurgitation. Adopting claimant's argument that inter-reader variability would expand the range of moderate mitral regurgitation by  $\pm 15\%$  would allow a claimant to recover benefits with an RJA/LAA as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.<sup>10</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Pickering's claim for Matrix Benefits.

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10. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement that "[t]here is no reasonable medical basis for the Attesting Physician's claim that [Ms. Pickering] has moderate mitral regurgitation, even taking into account inter-reader variability."